

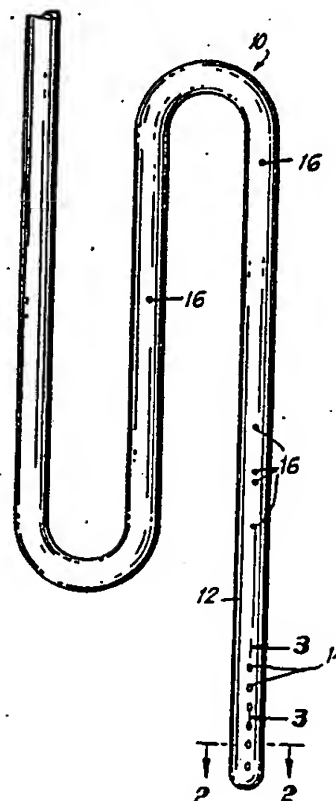


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

| | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (51) International Patent Classification⁴ : A61M 31/00, B26D 3/00 B22C 9/24 | A1 | (11) International Publication Number: WO 89/ 02290 (43) International Publication Date: 23 March 1989 (23.03.89) |
| (21) International Application Number: PCT/US88/03063 (22) International Filing Date: 7 September 1988 (07.09.88) (31) Priority Application Numbers: 098,097 227,397 (32) Priority Dates: 17 September 1987 (17.09.87) 2 August 1988 (02.08.88) (33) Priority Country: US (71) Applicant: NEURODYNAMICS, Inc. [US/US]; 400 East 70th Street, New York, NY 10021 (US). (72) Inventors: GHAJAR, Jamshid, B., G. ; 265 East 66th Street, New York, NY 10021 (US). HARIRI, Robert, J. ; 435 East 70th Street, New York, NY 10021 (US). GHAREMANI-GHADJAR, Fathali ; 1365 York Avenue, New York, NY 10021 (US). | | (74) Agent: MARSHALL, Jonathan, A.; Pennie & Edmonds, 1155 Avenue of the Americas, New York, NY 10036 (US). (81) Designated States: AT (European patent), AU, BE (European patent), BR, CH (European patent), DE (European patent), DK, FI, FR (European patent), GB (European patent), IT (European patent), JP, KR, LU (European patent), NL (European patent), NO, SE (European patent), SU. Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i> |

(54) Title: ANGLED HOLE VENTRICULAR CATHETER**(57) Abstract**

A catheter (10) for placement into the ventricular system of the brain of a subject comprising a flexible elongated body having a wall thickness sufficient to contain and transport fluid therein and having a forward end (12) and tip for insertion into the ventricular system of the brain of a subject; and a plurality of spaced apertures (14) located in the forward end (12) of the body spaced from the tip, each of the apertures (14) extending through the wall thickness at an angle such that a portion of the wall thickness is visible when viewing the aperture (14) perpendicular to the longitudinal axis of the body, thereby to minimize abrasion of brain tissue upon insertion of the catheter and to prevent choroid plexus and ependymal tissue from growing into the catheter apertures (14), thereby providing improved flow of fluid into or from said ventricular system. Also, methods of using and apparatus for making such catheters are disclosed herein.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

| | | | | | |
|----|------------------------------|----|------------------------------------------|----|--------------------------|
| AT | Austria | FR | France | ML | Mali |
| AU | Australia | GA | Gabon | MR | Mauritania |
| BB | Barbados | GB | United Kingdom | MW | Malawi |
| BE | Belgium | HU | Hungary | NL | Netherlands |
| BG | Bulgaria | IT | Italy | NO | Norway |
| BJ | Benin | JP | Japan | RO | Romania |
| BR | Brazil | KP | Democratic People's Republic of Korea | SD | Sudan |
| CF | Central African Republic | KR | Republic of Korea | SE | Sweden |
| CG | Congo | LI | Liechtenstein | SN | Senegal |
| CH | Switzerland | LK | Sri Lanka | SU | Soviet Union |
| CM | Cameroon | LU | Luxembourg | TD | Chad |
| DE | Germany, Federal Republic of | MC | Monaco | TG | Togo |
| DK | Denmark | MG | Madagascar | US | United States of America |
| FI | Finland | | | | |

ANGLED HOLE VENTRICULAR CATHETER

TECHNICAL FIELD

5 The present invention relates to a ventricular catheter having specifically angled apertures which facilitate access to or drainage of cerebral spinal fluid and certain methods of making and using same.

BACKGROUND OF THE INVENTION

10 The four ventricles of the human brain are interconnected cavities that produce and circulate cerebral spinal fluid (CSF). Procedures involving ventriculostomy, i.e., placement of a catheter into the ventricular system of the brain, form a major part of a neurosurgeon's clinical practice. General areas of application of ventricular catheter placement include intracranial pressure monitoring (ICP), draining or shunting of CSF and the instillation of pharmacological therapeutic agents.

15 CSF drainage is essential for patients with congenital or acquired hydrocephalus. CSF drainage, which can only be performed with an intraventricular catheter, is a life-preserving procedure, because it can immediately reduce intracranial pressure. The ventricular catheter, used to drain CSF, is connected to a peripheral subcutaneous drainage system, i.e., to the peritoneal cavity or systemic circulation via the heart or in the case of ICP to an external drainage collection system. Standard procedures for ventricular catheterization are disclosed in the textbook literature. See, for example, Neurosurgery, edited by Robert H. Wilkins and Setti S. Rengachary, Section A, Chapter 13, Techniques of Ventricular Puncture (McGraw Hill 1984).

20 The most frequently chosen site for ventricular catheterization is coronal. In most cases, a catheter is inserted in the anterior horn of the lateral ventricle through an orifice or burr hole drilled just anterior to the coronal suture in the midpupillary line of the cranium, i.e.,

in the frontal bone over the ventricle. The burr hole, only slightly larger than the diameter of the selected catheter to insure a snug fit and provide a seal against CSF leakage, is placed approximately 1 cm anterior to the coronal suture, approximately 10 to 12 cm above the nasion, and approximately 2 to 3 cm from the midline over the nondominant hemisphere. After the burr hole is made, the dura and underlying pia-arachnoid are opened and coagulated, for example, with a fine-tipped blade after cauterizing the dural surface.

The lateral ventricles of the human brain form an arc parallel to the arc of the cranium, i.e., the contour of the lateral ventricles parallels the arc of the surface of the skull. Thus, a catheter guided perpendicular to the cranial surface at the point of entry into the cranium will enter the ventricular system. Specifically, any line penetrating a burr hole in the surface of the skull at a 90° angle also bisects the lateral ventricle.

A more recently developed procedure to ensure correct catheter placement is disclosed in U.S. Patent No. 4,613,324. The apparatus comprises a guide assembly which, when positioned over an orifice drilled in the cranium above the anterior horn of the lateral ventricle, guides a catheter and obturator through the orifice and into the lateral ventricle at an angle normal to an imaginary plane formed by a tangent to the cranium at the orifice, while the corresponding method comprises providing an orifice in the cranium just anterior to a coronal suture in a midpupillary line of the cranium and inserting a ventricular catheter containing an obturator through the orifice towards a lateral ventricle, wherein the catheter containing the obturator is guided through the orifice, by means of a novel guide assembly, at an angle normal to an imaginary plane formed by a tangent to the cranium at the orifice.

A wide variety of catheters are known in the prior art for the purpose of penetrating the ventricular cavity. Such catheters are typically in the form of a hollow tube which is provided with a plurality of apertures at the ventricular or inflow end to permit the passage of CSF from the brain into the catheter and thence to the bloodstream or peritoneal cavity of the patient or to an external drainage system. However, malfunctions frequently occur with such a catheter due to the blockage of the apertures in the inflow end of the catheter. Such blockage is usually caused by the growth of choroid plexus or ependymal tissue within the ventricle into the apertures in the inflow end of the catheter. This tissue may block the apertures in the inflow end of the catheter in a relatively short period of time after the catheter has been inserted into the ventricle thereby rendering the catheter inoperative in relieving excess pressure due to the build-up of CSF within the ventricle. Furthermore, prior art catheter apertures are cut perpendicular to the length of the catheter, thus causing abrasion of brain tissue when the catheter is inserted.

The likelihood of ventricular catheter malfunction by aperture plugging with brain tissue can be lessened by angling the aperture holes in the wall of the catheter such that there is "no see through" flow from the outside to the inside of the lumen. Also, by positioning the rows of apertures 120° apart there is essentially no chance for direct ingrowth of ventricular tissue therethrough. In addition, the apertures are angled away from the direction of the insertion of the catheter into the brain thus lessening the chance of brain abrasion. Further, by slightly stretching the catheter by means of the stylet (which is integral to the catheter and used for placement of it into the brain) the holes will close so that no opening will be

visible during the placement thereof, with the holes re-
opening after the tension on the catheter is relieved by
5 removal of the stylet.

As such, it would be desirable to provide a
catheter which overcomes the problems of previously devised
ventricular catheters which are emplaceable within a
ventricle of a human brain to control the flow of excess
10 fluids to or from the brain. The present invention provides
a simple solution which resolves the problems of prior art
catheters in a novel and unexpected manner.

SUMMARY OF THE INVENTION

15 The present invention relates to a catheter for
placement into the ventricular system of the brain of a
subject comprising a flexible elongated body having a wall
thickness sufficient to contain and transport fluid therein.
The body has a forward end and tip for insertion into the
20 ventricular system and a plurality of spaced apertures
located in the forward end of the body spaced from the tip.
Each of the apertures extends through the wall thickness at
an angle such that a portion of the wall thickness is visible
when viewing the aperture perpendicular to the axis of the
25 body. This arrangement facilitates closure of the apertures
by slightly stretching the body with a placement stylet to
minimize abrasion of brain tissue upon insertion of the
catheter. This arrangement also helps prevent choroid plexus
tissue from growing into the catheter apertures, thereby
30 providing improved flow of fluid into or from the ventricular
system.

Preferably, each of the apertures extends through
the wall thickness at an angle of about 35° with respect to
the longitudinal axis of the body, and a plurality of
35 apertures are aligned in a number of rows. Also, rows of

-5-

these apertures are spaced 120° apart around the circumference of the body for maximizing the structural integrity of the catheter forward end.

If desired, the forward end of the body can be made of a radioopaque material at least in the area surrounding the apertures to facilitate monitoring of catheter placement. The body may include means to indicate the depth of penetration of the catheter forward end to assist in proper placement thereof. These depth penetration indication means may be markings of a radioopaque material to facilitate monitoring of the placement of the catheter.

The invention also relates to method of accessing CSF in a ventricle within a human cranium which comprises drilling an orifice in the cranium just anterior to a coronal suture in a midpupillary line of the cranium, and guiding a catheter through the orifice by means of a guide assembly in a direction perpendicular to an imaginary plane defined by a tangent to the cranium at the orifice. The catheter thus accurately penetrates the ventricle on the first insertion with minimal abrasion of brain tissue. The catheter, described above, i.e., one having the appropriate positioning and configuration of apertures to minimize ventricular tissue growth thereinto, is preferred so that increased flow of fluid to or from the ventricle is obtained.

The catheter of this method utilizes a guide assembly comprising tubular means and support means for the tubular means. Therefore, the method further comprises placing the support means so as to rest unsecured on the human cranium in surrounding spaced relation to the orifice, and guiding the catheter through the tubular means, into the orifice and into the ventricle. The support means and tubular means are related to each other such that the catheter is guided through the orifice by the tubular means

-6-

in a direction perpendicular to an imaginary plane defined by a tangent to the cranium of the orifice, independent of the orifice. To accomplish this, the tubular means is supported through a support means comprising a plurality of legs of equal length.

Also, this method further comprises inserting a removable insert within the tubular means to reduce the diameter thereof for receiving the catheter. A stylet may be utilized to assist in the insertion of the catheter in a manner such that the catheter is stretched so as to flatten the apertures to further reduce abrasion of brain tissue upon insertion therein. In a preferred arrangement, the catheter body includes means for indicating the depth of penetration of the catheter forward end so that the method further comprises inserting the catheter to a predetermined depth into the ventricle. The indicating means may be radioopaque markings so that the placement of the catheter in the ventricle can be monitored.

The present invention also relates to an apparatus for making catheters having a plurality of angled holes in a flexible, elongated body. Generally, such catheters are hollow elongated members having a plurality of apertures near one end. One embodiment of this apparatus comprises an insert and a molding assembly. The insert includes rod means for forming the plurality of apertures of a predetermined size and shape and means for forming and supporting the bore of the elongated member: the rod means being positioned at a predetermined orientation with respect to the bore forming means so that the hollow elongated member receives a plurality of apertures at a predetermined position, orientation and dimension.

-7-

The molding assembly includes means for forming and supporting the hollow elongated member, a plurality of guide
5 holes in the forming means for at least partially receiving the rod means to properly orient the insert therein, and means for allowing a polymerizable liquid to be introduced into the space between the insert and the molding assembly to form the catheter by polymerization therein. Preferably, the
10 rod means and bore forming means of the insert are integral and made of a material which is capable of withstanding temperatures caused by polymerization of the polymerizable liquid.

Generally, the forming and supporting means is
15 constructed in the form of a hollow elongated cylinder having an open end and a closed end wherein the insert is introduced into the open end in a manner such that the rod means extends into a respective guide hole in the cylinder. These rod means and corresponding cylinder holes can be oriented in a
20 spiral configuration around the circumference of the bore forming means or at predetermined stepped intervals along the length of the bore forming means.

The invention also contemplates an apparatus for cutting apertures in a hollow elongated member which
25 comprises a cutting assembly having means for cutting a plurality of apertures of a predetermined size, and a holding assembly. The holding assembly includes means for supporting and substantially completely surrounding a portion of a hollow elongated member in the vicinity where apertures are
30 to be made; means adjacent the supporting means for guidably directing the cutting assembly through the supporting means for cutting contact with the hollow elongated member at a predetermined angle thereto; and means operatively associated with the directing and supporting means for positioning the
35 portion of the hollow elongated member at a predetermined

orientation with respect to the cutting assembly so that the hollow elongated member can be placed into the holding
5 assembly in a manner to receive a plurality of apertures therein at a predetermined position, orientation and dimension.

The holding assembly preferably comprises a holding block containing an elongated aperture of a size and
10 dimension slightly larger than that of the hollow elongated member so that the member can be easily and removably inserted into the elongated aperture, while the cutting assembly comprises a plurality of elongated rods. The directing means correspondingly comprises a plurality of
15 elongated guide apertures corresponding to the rods of the cutting apparatus but being of slightly greater size and dimension so as to allow the rods to easily and removably pass therethrough for cutting the apertures in the hollow elongated member.

The positioning means includes a stop member for
20 prevention of insertion of an end of the hollow elongated member beyond a predetermined point in the elongated aperture of the holding block, which is advantageously in the shape of a cube with the elongated aperture extending along a diagonal line passing through the center of the cube.
25

In the most preferred construction, the directing means comprises three sets of elongated apertures, each set being spaced from the others so that the hollow elongated member is provided with rows of apertures spaced 120° apart
30 along its outer periphery. Thus, each of the sets of elongated apertures of the directing means would extend along a diagonal line across a face of the holding block cube to achieve this result.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention are described hereinbelow with reference to the drawing figures wherein:

FIG. 1 is a perspective view of a catheter according to the invention;

FIG. 2 is a cross-sectional view taken along line 2--2 of FIG. 1;

FIG. 3 is a cross-sectional view taken along line 3--3 of FIG. 1;

FIG. 4 is a perspective view of an apparatus for holding the catheter during the cutting of apertures therein;

FIG. 5 is a top view of the apparatus of FIG. 4;

FIG. 6 is a section taken along lines 6--6 of FIG. 5 over which is shown an apparatus for cutting apertures in the catheter;

FIG. 7 is an enlarged view of the cutting apparatus piercing the catheter sidewall when the catheter is placed in the holding apparatus of FIG. 4;

FIG. 8 is a perspective view of a symmetric molding insert according to the invention;

FIG. 9 is a perspective view of a spiral molding insert according to the invention;

FIG. 10 is a cross sectional view of a mold housing for use with the insert of FIG. 8;

FIG. 11 is a cross sectional view of a mold housing for use with the insert of FIG. 9;

FIG. 12 is a cross sectional view of the mold of FIG. 10 taken along lines 12--12 thereof; and

FIG. 13 is a cross sectional view of the mold of FIG. 11 taken along lines 13--13 thereof.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring initially to FIG. 1 there is illustrated
5 catheter 10 which is intended for insertion into a ventricle
of the human brain for access to or drainage of CSF such as;
for example, would be necessary to drain excess CSF during
treatment of hydrocephalus. Since the present invention is
primarily concerned with the forward or insertion end of the
10 catheter, a detailed description of the opposite or out flow
end of the catheter is not provided as such details are well
known in the relevant surgical art.

This catheter 10 is a flexible, hollow, elongated
member having a sufficient wall thickness for the containment
15 and or transport of fluids therein and therethrough. The
forward end 12 of the catheter includes a plurality of
apparatus 14 for access to CSF in the ventricle of the brain.
By "access" what is meant is contact of CSF for removal or
drainage from the brain or, conversely, to enable medicaments
20 or other fluids to be directed or delivered into the brain
from the catheter through the apertures 14. These apertures
14 are positioned and configured in a predetermined manner so
as to allow for a better and more continuous flow of fluids
in and through the catheter with less chance of plugging the
25 holes due to ingrowth of a brain tissue when the catheter is
placed in the ventricle. Further, the design of the holes
enables the catheter placement to be made in an improved,
easier manner while causing less abrasion damage to tissue
during insertion of the catheter.

30 As shown in FIGS. 2 and 3, the catheter 10 is
designed with 3 sets of holes set 120° apart. These holes
are cut at an angle into the wall of the catheter such that
the angle of the cut is measured along the longitudinal axis
of the catheter in the direction of movement of the catheter
when it is inserted into the ventricle. Further, the
35

-11-

diameter of each hole in the catheter is proportional to the thickness of the catheter wall so that, as best illustrated in FIG. 3, there is no direct linear visual access to the interior of the catheter when the holes are viewed perpendicular to the longitudinal axis of the catheter.

By preparing the holes in this manner, abrasion of brain tissue is minimized upon insertion of the catheter into the ventricle, so less brain tissue is destroyed as a direct result of such decreased abrasion. Further, by stretching the catheter slightly, the holes in the catheter are closed thus preventing such tissue as may come in contact with the catheter from entering the lumen upon insertion. The stretching of the catheter can easily be accomplished when a rigid placement stylet is used: the body of the catheter being slightly pulled back from the insertion end while the stylet is held, thus allowing the holes to be somewhat flattened. This lack of direct access to the inside of the catheter prevents the growth of brain cells or tissue therein, thus resolving one of the major causes of plugging and malfunction of prior art catheters which utilize 90° or perpendicular apertures. The 120° peripheral offset for each set of holes further minimizes the possibility that choroid plexus or brain cell growth will extend across the inner diameter of the catheter even if such growth does penetrate into one or more of the holes.

Although the holes are advantageously shown as being cut at an angle of 35° with respect to the longitudinal axis of the catheter, it is to be noted that other angles can also be used in this invention provided that direct access to the inside of the catheter is prevented. These other angles would be somewhat dependent upon wall thickness of the catheter, since heavier wall thicknesses would allow a greater range of angles while still preventing direct access

-12-

into the catheter interior. Suitable angles for any specific catheter construction can be determined from the relationship
5 $d \tan \theta = t$, where d is the diameter of the aperture, t is the wall thickness of the catheter, and θ is the angle between the cut of the aperture and the longitudinal axis of the catheter body. As shown by the relationship of these variables, the diameter of the aperture must be less than or
10 equal to the wall thickness of the catheter divided by the tangent of the angle. To calculate suitable angles for any particular aperture size and catheter wall thickness, the formula would be $\theta = \tan^{-1} \frac{t}{d}$, so that the tangent of the
15 angle, θ , is greater than the quotient of the thickness divided by the diameter.

To assist in the understanding of the invention, direct access is avoided when the diameter of the hole on the outside wall of the catheter does not overlap the diameter of
20 the hole on the inner wall catheter when viewed in a line perpendicular to the wall of the catheter. Thus, it is possible to utilize angles other than 35° although 35° has been found to be particularly advantageous.

By placing the holes to avoid direct access to the
25 inside of the catheter, it is possible to cut the holes larger in diameter than they would be if direct access was provided without weakening the structural integrity of the catheter. These larger holes allow for an increased flow of CSF into the catheter while also making it more difficult for
30 any possible brain cell growth to plug the entire hole, compared to the relatively smaller diameter holes of prior art catheters which provide direct access into the body of the catheter.

-13-

The catheter of the invention can be inserted into the ventricle of the brain in any manner currently known, including "freehand" or with the use of a guide. To assist in the proper location and placement of the catheter, a plurality of markings 16 are provided along the length of the catheter body. These markings correspond to predetermined insertion lengths of the catheter and enables the surgeon to know precisely how far the tip of catheter is inserted into the ventricle. By making these markings of a radioopaque material such as barium, the depth of placement of the catheter can easily be monitored by conventional techniques. Furthermore, if desired, the forward section of the catheter in the area around the apertures can also be made of a radioopaque material for viewing on various scanning equipment the precise placement of the forward end and tip of the catheter.

The improvements provided by the catheter of this invention are significant in that the physician does not require any guess work to determine the precise placement of the catheter in the patient's brain. Furthermore, when so placed, the catheter provides improved fluid delivery and/or removal with minimal disturbance of the surrounding brain cells while also discouraging brain tissue growth into the catheter apertures. As mentioned above, the catheter can be inserted in the brain in any manner commonly utilized. Rather than a "free hand" technique, it is advantageous to utilize a guide assembly to insure correct catheter placement.

A preferred guide apparatus and method of insertion of a catheter into the ventricle is disclosed in U.S. Patent No. 4,613,324, the disclosure of which is expressly incorporated herein by reference thereto. As shown in the patent, a stylet is used to assist in the insertion of the catheter.

-14-

As noted above, the stylet can be used to stretch the present catheters so that the angled apertures can be flattened to
5 minimize the abrasion of brain tissue during insertion. Also, this flattening operation slightly reduces the overall diameter of the catheter which further reduces such abrasion.

It is known for certain applications to utilize a second stylet for guiding the catheter into the ventricle.
10 In prior art catheters, this second stylet is inserted into one of the apertures at the forward end of the catheter. Since those apertures are cut at 90°, an unwieldy assembly is created. Any attempt to align the second stylet parallel to and adjacent the first stylet and catheter causes the tip to
15 be somewhat bent, thus causing further difficulties in its insertion and penetration of the ventricle. The present invention significantly reduces and minimizes this problem since the angled holes are more receptive to the introduction of the second stylet in a compact orientation (i.e., in a "V"
20 shape, rather than an "L" shape) which greatly enhances the manipulation of the catheter and stylets during placement in the ventricle.

The catheters of the invention can be easily manufactured in a highly accurate and reproducible manner by
25 utilizing the holding apparatus of the invention. FIG. 5 shows a holding apparatus 20 in the form of a machined metal block or cube 22. A longitudinal extending aperture 24 extends diagonally from one corner of the cube through the center to the opposite corner. The diameter of the aperture
30 24 is only slightly greater than the diameter of the catheter 10 so that the catheter is fully supported in the aperture when the angled holes are made in the catheter wall.

FIG. 6 illustrates a cutting apparatus 30 consisting of a handle 32 and a plurality of hollow tube like
35 cutting elements 34 each of which have a sharpened tip 36.

-15-

The tube elements 34 extend through guide apertures 28 on one face of the cube 22 until contact is made with the catheter 10. As best illustrated in FIG. 7, the cutting tubes 34 penetrate the catheter wall, thus forming the appropriately sized holes therein at the predetermined angle, position and configuration.

Prior art catheters, as noted above, have four sets of holes oriented 90° apart along the circumference of the catheter. In addition to weakening the strength and structural integrity of the catheter in the tip area, holes on opposite sides of the catheter (i.e., those 180° apart) are made simultaneously by a punching tool. This results in holes on one side being larger in diameter than those on the opposite side. Therefore, two sets of holes are large and two are small. This non-uniformity affects CSF flow and the smaller holes can easily become blocked by brain tissue growth, thus causing reduced operation of those catheters.

The present invention resolves these problems by accurately and precisely placing three sets of uniform holes cut at the desired angle to the catheter body and spaced apart exactly by 120°. This results in increased flow through the holes, higher strength and integrity of the catheter body, and greater ease of insertion and placement of the catheter in the ventricle.

FIGS. 4 through 6 illustrate the placement of guide apertures 28 on the various faces of the cube. In a most preferred arrangement, these guides are positioned in a diagonal line along the top and two side faces of the cube 22, so that each set of holes is placed 120° apart around the periphery or circumference of the catheter body. As noted previously, it is highly advantageous to make the holes in the catheter 10 at an angle of 35° with respect to the longitudinal axis of the catheter.

-16-

This apparatus guarantees the accuracy of the hole cutting at the appropriate angle as well as the precise spacing of the holes relative to each other around the periphery or circumference of the catheter. To cut the holes, the user merely inserts the tubes 34 of cutting apparatus 30 into the guides 28 when a catheter is placed in the holding block 20. The cutting apparatus 30 after piercing the catheter wall 10 is then removed, resulting in placement of the holes at the precise orientation and configuration in a simple manner which allows for repeatable and rapid production of such angled hole catheters. Further, the precision obtained in utilizing this apparatus is very high and reproducible to facilitate mass production.

The preceding apparatus has been found to be suitable for constructing apertured catheters of a variety of materials for particular applications. When very small diameter holes in thin-walled silicone catheters are desired, the quality of side-wall smoothness necessary to prevent cells or tissue from binding and plugging the catheter holes is difficult to obtain by the use of the cutting apparatus. Accordingly, applicants have devised a molding system which achieves all the desired results. This embodiment illustrated in FIGS. 8 through 13, is discussed below. Generally, a disposable insert is placed in a molding assembly prior to the injection of the polymerizable silicone material. This insert is retained in place until the silicone material cures. Thereafter, the insert and catheter are removed from the mold and the insert is discarded. This technique enables the user to produce extremely smooth, very small, angled holes at any orientation, position or configuration in a relatively simple and highly reproducible manner.

-17-

FIGS. 8 and 9 illustrate two preferred disposable inserts 50, 55. Each of these inserts has an elongated body portion 52, 57 and a plurality of rod like extensions 52, 54 extending from the body at a predetermined angle. As mentioned above, it is highly advantageous to make the holes of the catheter at an angle of 35 degrees with respect to its longitudinal axis. Thus, the rod - like extensions 52, 59, of these inserts are positioned at an angle preferably of 35 degrees with respect to the axis of the body member 52, 57. Fig. 8 illustrates an insert for forming three rows of apertures in the catheter, while FIG. 9 illustrates a spiral orientation of such apertures about the circumference of the catheter body.

FIGS. 10 through 13 illustrate the molding cylinders 60, 80 for use with the previously described inserts 50, 55. Each mold includes an open end 62, 82 which enables insertion of the corresponding inserts 50, 55, and a closed end 64, 84 which is used to form the insertion tip of the catheter. These molds 60, 80 include a plurality of guide apertures 66, 86 for at least partially receiving the rod like members 52, 59 of the respective inserts 50, 55. The guide holes 66, 86 extend through the wall 68, 88 of the molding cylinders 60, 80 at an angle which corresponds to the desired angle of the catheter holes.

In manufacturing, a plurality of molds 60, 80 and a much greater number of inserts 50, 55 are prepared. Since the molds 60, 80 are reusable, basically any material can be used which would provide a useful service life. This would include, for example, steel, stainless steel, aluminum, etc. and certain engineering thermoplastics may also be suitable. These materials must be sufficiently strong to retain the insert and withstand the temperatures anticipated for the

-18-

polymerization of the material used to form the catheter.
Such mold material must also be dimensionally stable over the
5 entire curing temperature range.

The insert 50, 55 should be made of a self-lubricating material that does not bind or stick to the polymerizable liquid used to form the catheter. Also, the self-lubricating material must be sufficiently flexible so
10 that it can be easily inserted and drawn out of the mold without damaging the catheter. At this time, the most preferred material for the insert is an injection molded polyamide material.

A preferred material for the catheter itself, is a
15 polymerizable silicon liquid which has a very low injection and curing temperature, i.e., about 100°F. While this requires a relatively long curing time, high production rates can be achieved through the use of multiple molding cavities. The inserts are disposable so that each insert can only be
20 used to make one catheter. As noted above, the mold itself can be reused an infinite number of times.

During manufacturing, after the insert is placed within the mold, and the rod member properly positioned within the guide holes of the mold, the polymerizable liquid
25 is introduced into the space between the insert and the mold. The liquid is then allowed to polymerize and cure to form the catheter. The insert and catheter are removed from the mold and the insert is then destroyed to form the final catheter product.

30 The preceding molding technique provides numerous advantages, including:

- 5 1) the catheter holes can be configured in any shape or size relative to the axis of the catheter. For example, spiral, off-set 90 degree or off-set 120 degree holes can easily be obtained.
- 10 2) the angle of the hole relative to the axis of the catheter can be easily changed by providing different mold inserts and mold cavities. This allows optimization of the hole angle compared to the hole diameter as a function of cell growth. This relationship is governed by the formula given above.
- 15 3) this apparatus assures that no "flashing" will occur on the internal bores of the catheter. Any excess material due to "flashing", will be visible on the exterior surface of the catheter and can be easily trimmed therefrom.
- 20 4) this apparatus assures that each catheter can be manufactured to very close tolerances with little or no variation in the construction of each device: hence, a high degree of reproducibility in mass production is achieved.

25 While it is apparent that the invention herein disclosed is well calculated to fulfill the objects above stated, it will be appreciated that numerous modifications and embodiments may be devised by those skilled in the art, and it is intended that the appended claims cover all such
30 modifications and embodiments as fall within the true spirit and scope of the present invention.

-20-

THE CLAIMS

5 What is claimed is:

1. A catheter for placement into a host comprising
a flexible elongated body having a wall thick-
ness sufficient to contain and transport fluid therein and
10 having a forward end and tip for insertion into the host; and
a plurality of spaced apertures located in
said forward end of said body spaced from said tip, each of
said apertures extending through the wall thickness at an
angle such that a portion of said wall thickness is visible
15 when viewing said aperture perpendicular to the axis of said
body, and such that upon slight stretching of the catheter by
means of a placement stylet the apertures will close upon
themselves and reopen upon removal of the tension on the
catheter, thereby to minimize abrasion of tissue upon
20 insertion of said catheter and to prevent tissue from growing
into said catheter apertures, thereby providing improved flow
of fluid into or from said ventricular system.

2. The catheter of claim 1 wherein each of said
25 apertures extends through said wall thickness at an angle of
about 35° with respect to the longitudinal axis of said body.

3. The catheter of claim 1 wherein said apertures
are aligned in rows which are spaced about 120° apart around
30 the circumference of said body.

-21-

4. The catheter of claim 1 wherein said forward
end of said body is made of a radioopaque material at least
5 in the area surrounding said apertures to facilitate monitor-
ing of the placement of said catheter in the ventricular
system.

5. The catheter of claim 1 wherein said body fur-
10 ther comprises means to indicate the depth of penetration of
said catheter forward end.

6. The catheter of claim 5 wherein said means
comprises markings of a radioopaque material to facilitate
15 monitoring of the placement of said catheter.

7. A method of accessing cerebral spinal fluid in
a ventricle within a human cranium which comprises:
drilling an orifice in the cranium just anter-
20 ior to a coronal suture in a midpupillary line of the cran-
ium; and

guiding a catheter through the orifice by
means of a guide assembly in a direction perpendicular to an
imaginary plane defined by a tangent to the cranium at the
25 orifice, whereby the catheter accurately penetrates the
ventricle on the first insertion with minimum abrasion of
brain tissue, said catheter comprising a flexible elongated
body having a wall thickness sufficient to contain and
transport fluid therein and having a forward end and tip for
30 insertion into said ventricle, and a plurality of spaced
apertures located in said forward end of said body spaced
from said tip, each of said apertures extending through the
wall thickness at an angle such that a portion of said wall
thickness is visible when viewing said aperture perpendicular
35 to the axis of said body,

-22-

whereby the position and configuration of said apertures of said catheter minimizes or prevents choroid plexus or ependymal tissue growth thereinto, so that increased flow of fluid to or from said ventricle is obtained.

8. The method of claim 7 wherein said guide assembly comprises tubular means and support means for said tubular means, said method further comprising placing said support means so as to rest unsecured on said human cranium in surrounding spaced relation to said orifice, and guiding said catheter through said tubular means and into said orifice and said ventricle, said support means and said tubular means being related to each other such that said catheter is guided through said orifice by said tubular means in a direction perpendicular to an imaginary plane defined by a tangent to the cranium of the orifice, independent of said orifice.

9. The method of claim 7 which further comprises supporting said tubular means through a support means comprising a plurality of legs of equal length, and inserting a removable insert within said tubular means to reduce the diameter thereof.

10. The method of claim 7 which further comprises utilizing a stylet to assist in the insertion of said catheter in a manner such that the catheter is stretched so as to flatten said apertures to further reduce abrasion of brain tissue upon insertion therein.

-23-

11. The method of claim 7 wherein said catheter body further comprises means for indicating the depth of penetration of said catheter forward end and wherein said method further comprises inserting said catheter to a predetermined depth into the ventricle.

12. The method of claim 11 wherein said indicating means comprises radioopaque markings and wherein said method further comprises monitoring the placement of said catheter in the ventricle.

13. An apparatus for making a hollow elongated member having a plurality of apertures therein comprising:
a first component including means for supporting a hollow elongated member in a predetermined position and orientation for formation of a plurality of apertures therein; and

a second component including means for forming said plurality of apertures at a predetermined position and orientation and of predetermined dimensions thereof in said hollow elongated member; the aperture forming means of said second component being guided by and at least partially received within said first component for achieving said predetermined position, orientation and dimension of said apertures.

14. The apparatus of claim 13 wherein said second component comprises means for cutting said plurality of apertures in said hollow elongated member, wherein said cutting means is guided by and received in one or more alignment holes in said first component so that said apertures are formed at said predetermined position, orientation and dimension.

15. The apparatus of claim 14 wherein said cutting means includes a plurality of elongated tubes and wherein
5 said first component comprises a holding block having at least one elongated bore of a size and dimension slightly greater than that of said hollow elongated member so that said member can be supported by said bore yet easily and removably inserted thereinto, and wherein a plurality of said
10 alignment holes correspond to the number of said cutting tubes and are of slightly greater size and dimension thereof so as to allow said tubes to easily and removably pass therethrough for cutting said apertures in said hollow elongated member at a predetermined angle.

15

16. The apparatus of claim 13 wherein the first component is a holding assembly comprising:

means for supporting a portion of a hollow elongated member in the vicinity where apertures are to be
20 made; said supporting means substantially completely surrounding said hollow elongated member;

means adjacent said supporting means for guidably directing said first component through said supporting means for cutting contact with said hollow
25 elongated member at a predetermined angle thereto; and

means operatively associated with said directing and supporting means for positioning said portion of the hollow elongated member at said predetermined orientation with respect to said second component, and
30 wherein the second component includes a cutting assembly.

17. The apparatus of claim 16 wherein the holding assembly comprises a holding block containing an elongated aperture of a size and dimension slightly larger than that of
35 said hollow elongated member so that said member can be

-25-

easily and removably inserted into said elongated aperture, wherein said cutting assembly comprises a plurality of
5 elongated rods, and wherein said directing means comprises a plurality of elongated guide apertures corresponding to said rods and being of slightly greater size and dimension so as to allow said rods to easily and removably pass therethrough for cutting said apertures in said hollow elongated member;
10 with the directing means having three sets of elongated apertures, each set being spaced from the others so that said hollow elongated member will be provided with apertures spaced about 120° apart along its outer periphery.

15 18. The apparatus of claim 16 wherein the positioning means comprises a stop member for prevention of insertion of an end of said hollow elongated member beyond a predetermined point in the elongated aperture of said holding block; wherein said holding block is a machined metal cube
20 with the elongated aperture extending along a diagonal line passing through the center of the cube; wherein each of said sets of elongated apertures of the directing means extends along a diagonal line across a face of the holding block cube; with the directing means having three sets of elongated
25 apertures, each set being spaced from the others so that said hollow elongated member will be provided with apertures spaced about 120° apart along its outer periphery.

30 19. The apparatus of claim 13 wherein said second component comprises a removable insert having an elongated body for forming the hollow interior portion of said hollow elongated member and a plurality of rod like members, extending from said body for forming said plurality of apertures, said first component including a plurality of

35

-26-

alignment holes for partially receiving said rod-like members
to thereby position said insert in said hollow member
5 supporting means.

20. The apparatus of claim 19 wherein said first
component comprises a hollow elongated cylinder having an
open end and a closed end wherein the insert is introduced
10 into the open end of said cylinder to form a hollow space
corresponding to the dimensions of the apertured elongated
member, and further wherein a polymerizable liquid is
introduced into said open end to form said apertured hollow
member by curing within said hollow space.

15

21. The apparatus of claim 13 wherein the first
component is a molding assembly comprising:

means for forming and supporting said hollow
elongated member by substantially completely surrounding said
20 hollow elongated member;

a plurality of guide holes located in said
forming means for at least partially receiving said second
component for proper orientation therein; and

means for allowing a polymerizable liquid to
25 be introduced into said molding assembly; wherein said
molding assembly and second component form a hollow space
therebetween corresponding to the dimension of the apertured
elongated member; and wherein the member is formed by
polymerization of the polymerizable liquid within the hollow
30 space; and

30

wherein the second component comprises::

rod means for forming said plurality of
apertures of a predetermined size and shape; and

means for forming and supporting a bore of
35 elongated member.

-27-

22. The apparatus of claim 20 wherein the rod means and bore forming means of the insert are integral and made of a material which is capable of withstanding temperatures caused by said polymerization of the polymerizable liquid; wherein the forming and supporting means comprises a hollow elongated cylinder having an open end and a closed end wherein the insert is introduced into the open end in a manner such that each of the rod means extends into a respective guide hole of said cylinder; and wherein the cylinder apertures and insert rod means are oriented in spiral configuration around the circumference of the bore forming means.

23. The apparatus of claim 20 wherein the rod means and bore forming means of the insert are integral and made of a material which is capable of withstanding temperatures caused by said polymerization of the polymerizable liquid; wherein the forming and supporting means comprises a hollow elongated cylinder having an open end and a closed end wherein the insert is introduced into the open end in a manner such that each of the rod means extends into a respective guide hole of said cylinder; and wherein the cylinder apertures and insert rod means are oriented in a spiral configuration around the circumference of the bore forming means.

24. The apparatus of claim 20 wherein the polymerizable liquid comprises a silicone and the insert is of an injection molded polyamide material and wherein the cylinder apertures and corresponding insert rod means are oriented at 120° intervals around the circumference of the bore forming means and wherein the cylinder apertures and corresponding insert rod means are distributed along the length of the bore forming means at said intervals.

FIG. 1

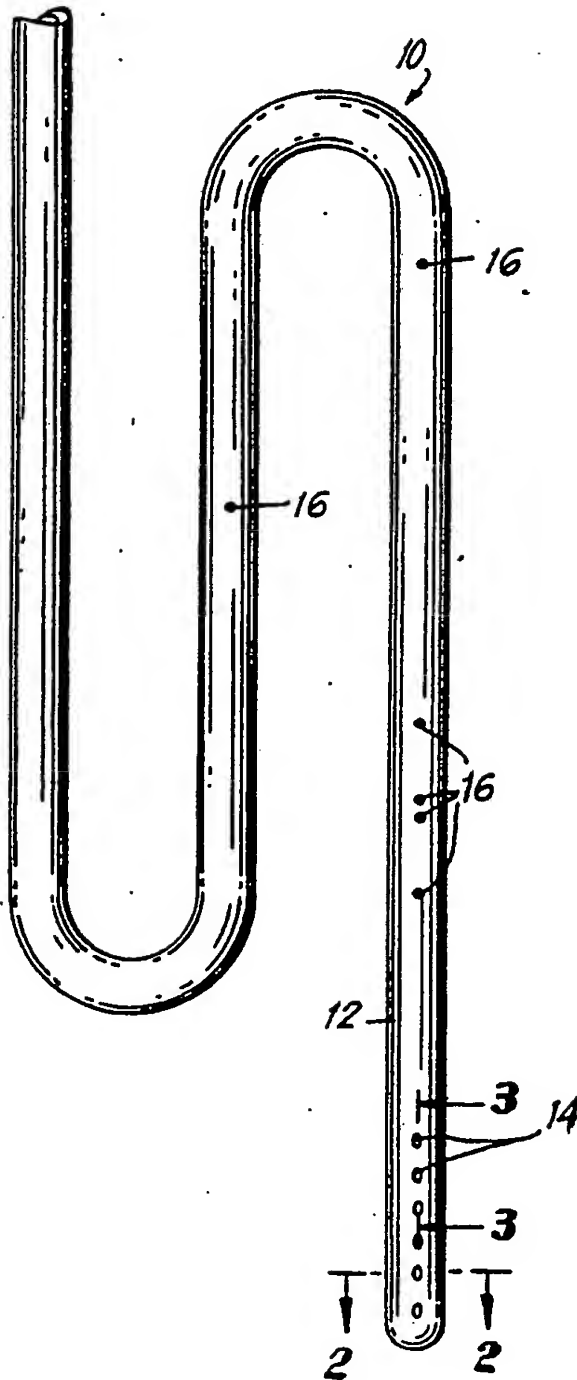


FIG. 2

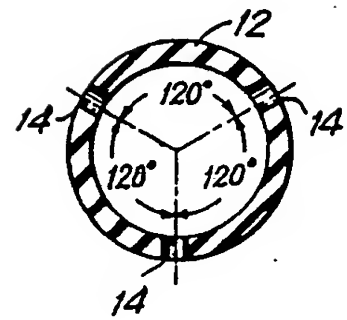


FIG. 3

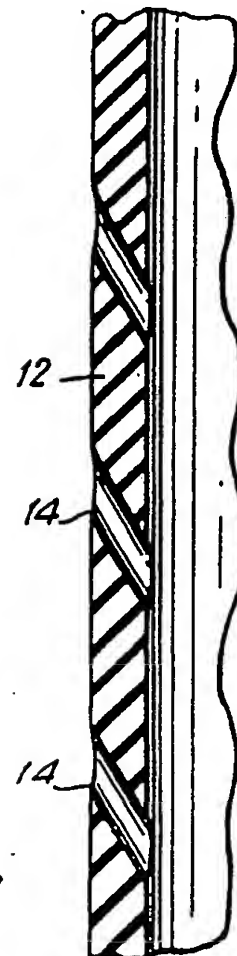


FIG. 4

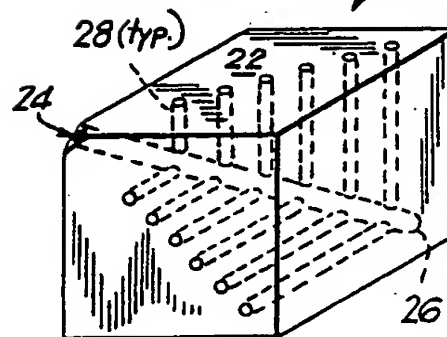
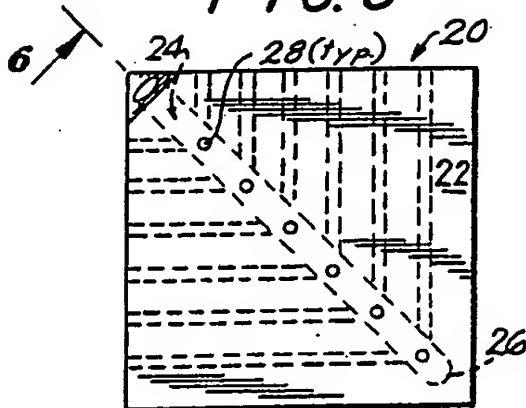


FIG. 5



6

FIG. 6

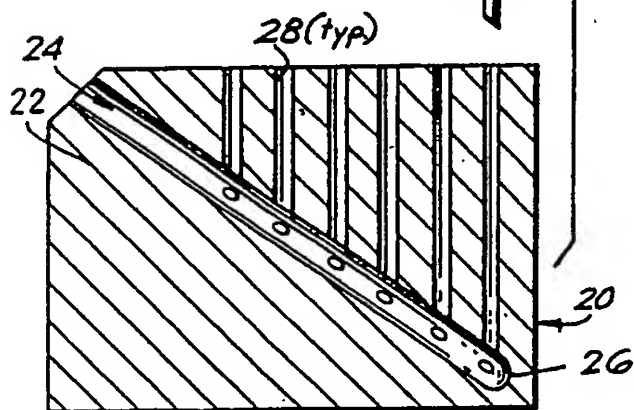
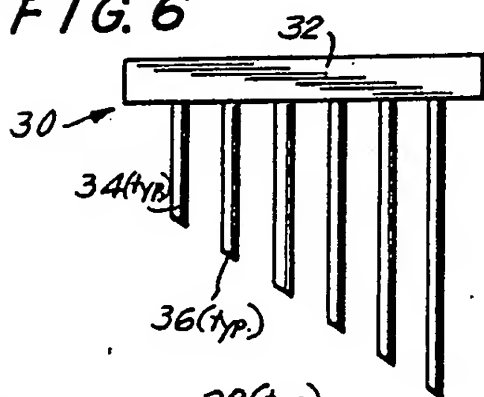


FIG. 7

FIG. 8

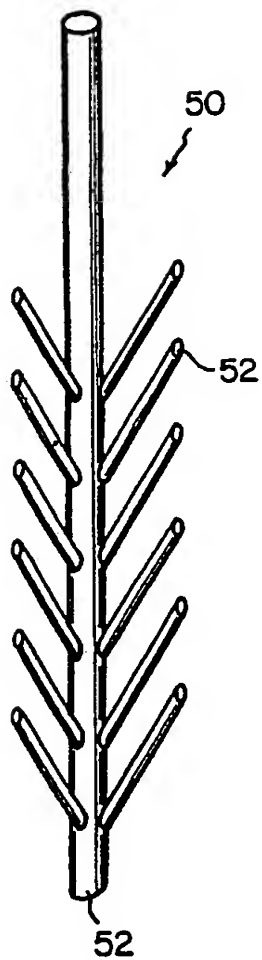


FIG. 9

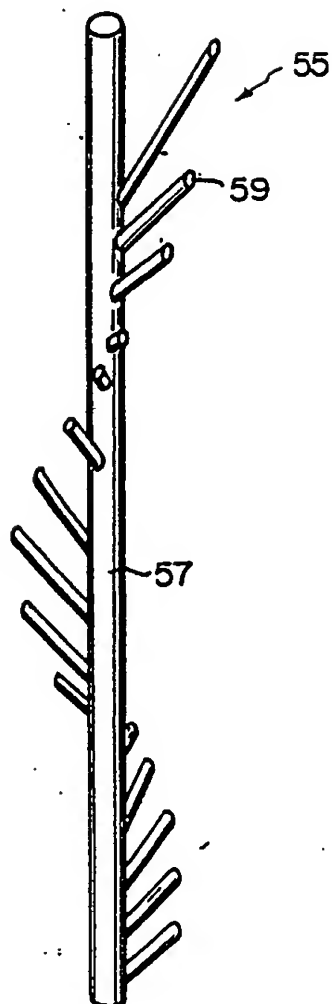


FIG. 10

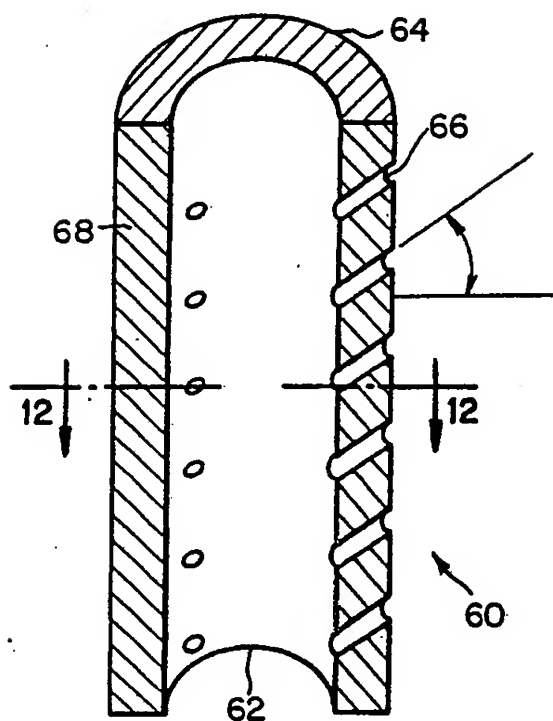


FIG. 11

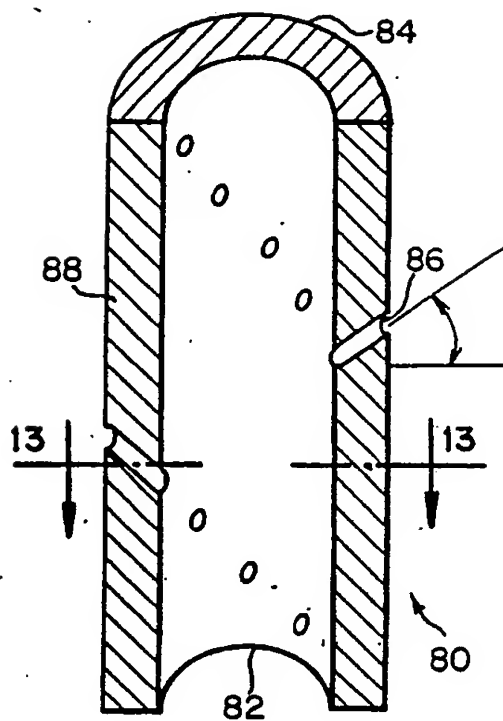


FIG. 12

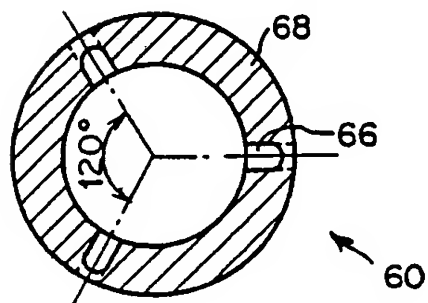
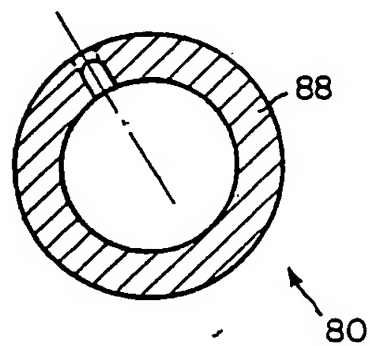


FIG. 13



INTERNATIONAL SEARCH REPORT

International Application No. **PT/US88703063**

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) *

According to International Patent Classification (IPC) and to the National Classification of the United States:

IPC (4): ABIM; 31/00; 8260 5/00; 822C 9/24
US CL: 604/49; 249/145; 83/54

II. FIELDS SEARCHED

Minimum Documentation Searched ?

| Classification System | Classification Symbols |
|-----------------------|------------------------------------------------------------------------------------------------------------------------|
| US | 604/8,9,10,49,51,280,281,282,264,256, 275,164,268,266,170 83/54, 184, 188 138/103 249/120,64,145,150,151,176,183 |

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched *

III. DOCUMENTS CONSIDERED TO BE RELEVANT *

| Category * | Citation of Document, ** with indication, where appropriate, of the relevant passages ¹² | Relevant to Claim No. ¹³ |
|----------------|-------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| Y _P | US, A, 4,737,152 (ALCHAS) 12 April 1988. See entire document. | 1-3 |
| Y _P | US, A, 4,769,005 (GINSBURG ET AL) 06 September 1988. See column 3, lines 1-41. | 1-3 |
| Y | US, A, 3,020,913 (HEYER) 13 February 1962. See column 2, lines 39-45 and 59-72, column 3, lines 57-61. | 1-3 and 7-12 |
| Y | US, A, 4,391,276 (LAZARUS ET AL) 05 July 1983. See column 2, lines 7-35 and column 4 lines 49-62. | 1-3 |
| Y | US, A, 2,393,003 (SMITH) 15 January 1946. See column 1, lines 39-45 and lines 52-53 and column 2 lines 1-7. | 1-3 |
| Y | US, A, 3,885,561 (CAMI) 27 May 1975. See column 2 lines 65-68, column 3, lines 1-20 and lines 51-55, and column 4, lines 14-20 and lines 34-36. | 1-6 |

* Special categories of cited documents: ¹⁰

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"A" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search

Date of Mailing of this International Search Report

29 November 1988

11 JAN 1989

International Searching Authority

Signature of Authorized Officer

Kathleen A. Daley
Kathleen A. Daley

ISA/US

| III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET) | | |
|----------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| Category * | Citation of Document, with indication, where appropriate, of the relevant passages | Relevant to Claim No |
| Y | US,A, 4,613,324 (GHAJAR) 23 September 1986. See column 3, lines 50-66 and column 4, lines 21-32. | 7-12 |
| Y | US,A, 3,747,450 (HUDSON) 24 July 1973. See column 1, lines 26-42 and column 2, lines 5-8 and lines 46-57. | 13-18 |
| Y | US,A, 3,739,461 (CUPLER, II) 19 June 1973. See column 2, lines 22-31 and column 4, lines 3-9 and lines 14-16. | 13-18 |
| Y | US,A, 3,996,832 (SCHUBERT ET AL) 14 December 1976. See column 1, lines 30-47 and column 2, lines 17-12 and lines 32-36. | 13-18 |
| Y | US,A, 3,489,045 (RAY, SR.) 13 January 1970. See column 2, lines 1-3, lines 40-43 and lines 48-59. | 13,19-24 |
| Y | US,A, 4,647,419 (HELPER ET AL) 03 March 1987. See column 2, lines 22-25 and lines 54-61, column 3, lines 10-19 and lines 47-68, and column 4, lines 1-11. | 12,19-24 |
| Y | US,A, 984,425 (GORMAN) 14 February 1911. See page 1, lines 28-31 and lines 70-74 and page 2, lines 8-33 | 13,19-24 |

| III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET) | | |
|----------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| Category * | Citation of Document, with indication, where appropriate, of the relevant passages | Relevant to Claim No |
| Y | US,A, 4,149,695 (QUICK ET AL) 17 April 1979. See column 2, lines 44-68, column 3, lines 1-4, lines 38-43, and lines 57-64, and column 10, lines 52-63. | 13,19-24 |
| Y,P | US,A, 4,750,877 (MCFARLANE) 14 June 1988. See column 3, lines 26-38 and lines 44-64, column 5, lines 65-69, column 6, lines 1-9, and column 7, lines 36-58. | 13,19-24 |
| Y | US,A, 1,544,856 (MURRAY) 09 September 1924. See column 1, lines 8-22. | 13,19-24 |

FURTHER INFORMATION

CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE¹

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers _____, because they relate to subject matter ¹² not required to be searched by this Authority, namely:

2. ☐ Claim numbers _____, because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out ¹³, specifically:

3. ☐ Claim numbers _____, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING²

This International Searching Authority found multiple inventions in this international application as follows:

I. Claims 1-12 drawn to a catheter and method of use of a catheter classified in class 604, subclass 49.

II. Claims 13-24 drawn to an apparatus for making a catheter classified in class 425, subclass 289.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- ☐ The additional search fees were accompanied by applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.